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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LY, CHEYNE D	
ART UNIT	PAPER NUMBER
2168	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/558,232	MANYAK ET AL.	
	Examiner	Art Unit	
	Cheyne D. Ly	2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43,58-105,107,108,110-129,132,139-142,144 and 145* is/are pending in the application.

4a) Of the above claim(s) *4-9, 11-13, 24-26, 29-32, 58, 65, 66, 69, 111-119,* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-3,10,14-23,27,28,33-43,59-64,67,68,70-105,107,108,110,120-129,132,139-142,144 and 145.

DETAILED ACTION

1. Applicants' arguments filed December 05, 2006 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied as necessitated by claim amendments. They constitute the complete set presently being applied to the instant application.
2. The CRF and Sequence Listing have been entered.
3. Claims 1-3, 10, 14-23, 27, 28, 33-43, 59-64, 67, 68, 70-105, 107, 108, 110, 120-129, 132, 139-142, 144, and 145, system comprising a memory of data about compounds and targets with interaction information, known compounds with known biological activity, have failed in pre-clinical or human clinical test, and molecular targets which include receptors, are examined on the merits.

RESPONSE TO ARGUMENTS

4. The rejections in the previous Office Action, mailed May 31, 2006, have been withdrawn as necessitated by claim amendments. Therefore, Applicant's argument directed withdrawn rejections are moot.

CLAIM REJECTIONS - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 10, 14-23, 27, 28, 33-43, 59-64, 67, 68, 70-76, 78-105, 107, 108, 110, 120, 121, 124-129, 132, 139-142, 144, and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al. (1997) (Weinstein hereafter) taken with Antman et al. (1992) (Antman hereafter).

MOTIVATION TO COMBINE

8. Antman et al. discloses an improvement for "better databases" for the treatment of patients in clinical trials (page 240, Conclusions §). While, Weinstein describes a method of selecting compounds clinical trials (page 344, column 1, lines 10-16) and providing clinical databases (page 348, column 2, lines 22-23). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by Antman et al. to modify the clinical database of Weinstein for better databases for the treatment of patients in clinical trials.

BASIS OF REJECTION

9. In regard to claims 1, 17, 33, 35, 37-40, 59-61, 63, 64, 132, 139, and 142, Weinstein describes a computer system comprising:

a. A first database containing, records corresponding to a plurality of chemical compounds and records corresponding to biological information related to effects of such chemical compounds on biological systems (page 344, column 2, line 4, to column 3, lines 4-22, especially, "chemical structure (S) database");

b. A second database containing records corresponding to a plurality of molecular targets (page 344, column 2, line 23, to column 3, line 22, especially, "target (T) database", and Figure 1, Database T);

c. A third database containing records corresponding to results from *in vitro* assays measuring interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database (, the results including information on the effect that a compound selected from the first database has on the interaction between a reference compound know to interact with a selected molecular target from the second database and said selected molecular target (page 344, Figure 1, especially, the text description of Database A); and

d. A user interface allowing a user to provide the system with information about a new chemical compound (page 343, column 3, last paragraph, especially, ""Given one compound as a 'seed'...", and page 344, column 1, lines 25-33, especially, "Portions of these databases can been accessed through DTP's World Wide Web site"); and

e. A query script that extracts information from the three databases that is relevant to the predictability of the potential use of the new compound as a drug (page 349, column 1, item 21, "especially, "DISCOVERY uses...scripting...").

10. However, Weinstein does not disclose the limitation of a first database of chemical compounds that have failed in preclinical or human clinical tests, as in instant claims 17 and 142, and as an option of the elected subject matter species.

11. Antman describes literature a search for meta-analyses and randomized control trials using the Medline database (page 241, column 2, last paragraph). The searches resulted in data directed to treatments that have no effect on mortality or are potentially harmful (page 240, Data Synthesis §) and "negative trial, suggesting that the treatment does not work" (failed in human clinical tests) (page 246, column 1, "Negative" RCTs §). Therefore, it would have been obvious to one of ordinary skill in the art to modify the clinical databases of Weinstein with information about "negative trial, suggesting that the treatment does not work" (failed in human clinical tests) as described by Antman for better databases for the treatment of patients in clinical trials.

12. In regard to claim 2, Weinstein describes the interaction includes binding and the effect includes inhibitory effect (page 343, column 2, lines 4-8, especially, "the NCI established a primary screen in which compounds are tested in vitro for their ability to inhibit...").

13. In regard to claims 3, 27, 41, 42, 103, and 125, Weinstein describes the chemical compounds includes compounds with known biological activity such as binding (page 343,

column 2, lines 4-8, especially, "the NCI established a primary screen in which compounds are tested in vitro for their ability to inhibit...").

14. In regard to claim 10, 67, 68, 108, and 110, Weinstein describes the molecular targets include receptors (page 344, column 2, line 35, especially, "cytokine receptors").

15. In regard to claims 14, 15, 18, 19, and 22, Weinstein describes the records of the first database corresponding to a plurality of chemical compounds are organized in categories related to the description and properties of the compounds (page 344, column 2, line 4, to column 3, lines 4-22, especially, "chemical structure (S) database").

16. In regard to claim 16, Weinstein describes the first database includes a natural product database (page 343, column 3, lines 5-7, and page 348, column 3, item 10, especially, "synthetic compounds and for natural product extracts").

17. In regard to claim 20, Weinstein describes the second database includes a sequence/mutation database (page 345, Figure 2, especially, the description of the figure "p53 seq, p53 sequence, wild-type versus mutant").

18. In regard to claim 21, Weinstein describes the second database includes a genomic database (page 348, column 2, "the plasticity of a poorly controlled genome...").

19. In regard to claim 23, Weinstein describe means for setting an interaction test threshold corresponding to said effect and means for selecting the compound when its results in a test meeting the interaction threshold (page 344, column 1, lines 10-16, especially, "five compounds...assessed in the screen and analyzed...selected for entry into clinical trials").

20. In regard to claims 28, 34, 36, 43, and 99, Weinstein describes the chemical compounds include compounds with known biological activity (page 344, column 2, line 4, to column 3, lines 4-22, especially, "chemical structure (S) database").

21. In regard to claim 62, Weinstein describes a fourth database containing records corresponding to the effect of chemical compounds contained in the first database on biological systems (page 344, Figure 1, especially, the text description of Database A).

22. In regard to claims 70 and 76, Weinstein describes the third database contains records corresponding to complete sets of results from a screening process ("the NCI established a primary screen in which compounds are tested in vitro for their ability to inhibit...").

23. In regard to claims 71-75 and 80, Weinstein describes records in the third database corresponding to the results of tests to determine the interaction between compounds in the first database and targets in the second database includes positive interactions and negative or lack of interactions (page 346, column 3, lines 11-12, especially, "highly negative", and page 347, column 1, lines 7-8, "correlate positively").

24. In regard to claims 78, 128, and 129, Weinstein describes the tests used to generate results comprising the third database are based on reporter gene assays or functional assays (page 343, column 2, lines 4-8, especially, "the NCI established a primary screen in which compounds are tested in vitro for their ability to inhibit growth of 60 different human cell lines", and page 346, column 3, lines 16-20, especially, "transport assays").

25. In regard to claims 79 and 81-86, Weinstein describes the limitation of determine interaction as numerical values (page 345, Figure 2, description of figure, especially, "high positive Pearson correlation coefficient...selective potency against cells that have less target or function", and page 346, Figure 4, especially, "Wilcoxon P value").

26. In regard to claims 87, 88, 95, 144, and 145, the limitations of LOPAC, United States Pharmacopeial Convention Inc.'s USP DI Series, and SMILES codes are directed to nonfunctional descriptive material. The limitations are directed to compilation of facts or data merely stored to be read without creating any functional interrelationship with the claimed subject matter. The MPEP states that when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability. For example, the claimed computer system differs from the prior art solely with respect to the limitation of LOPAC, United States Pharmacopeial Convention Inc.'s USP DI Series, or SMILES codes, nonfunctional descriptive material, that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer). See MPEP 2106, §VI. Therefore, the cited disclosure of Weinstein and Antman renders the claims obvious over the prior art.

27. In regard to claims 89-94, Weinstein describes records corresponding to the chemical compounds in the first database include at least a chemical name etc. (page 344, column 2, line 4, to column 3, lines 4-22, especially, "chemical structure (S) database"). The noted that the descriptors cited above have been reasonably interpreted as "can be analyzed using the

methods of recursive partitioning" because the method of Weinstein requires the "clustered correlation" (page 345, column 3, lines 5-26).

28. In regard to claims 96-98, and 120, Weinstein describes records corresponding to the chemical compounds in the first database include 3-D pharmacophore (page 344, column 2, line 4, to column 3, lines 4-22, especially, "chemical structure (S) database").

29. In regard to claims 100-102, 140, and 141, Weinstein describes the records in the first database corresponding to biological information includes information on chemical name...toxicity etc. (page 347, column 2, "genotoxic stress").

30. In regard to claims 104 and 127, Weinstein describes records in the first database corresponding to biological information related to mechanism of action of selected chemical compounds on biological systems includes information on at least one of the following categories: major pathway (page 347, column 2, "Activity Patterns and p53 Pathway Status").

31. In regard to claims 105 and 121, Weinstein describes records corresponding to biological information related to effects of the chemical compounds on biological systems can be searched and analyzed using computer based searching and data analysis methods (page 347, column 3, last paragraph).

32. In regard to claim 107, Weinstein describes such as value as GI50 (page 343, Abstract etc.). However, Weinstein does not explicitly describe the well known in the art numerical terms such as LD50, ED50, percent absorbed, half-life, and peak concentration for compound

activity. Weinstein "Each compound's pattern is like a fingerprint, essentially unique among the many billions of distinguishable possibilities (Abstract etc.). Further, patterns of activity observed in the screen have proved predictive in an even more powerful way at the molecular level (page 343, column 3, lines 18-20). Therefore, it would have been obvious for one of ordinary skill in the art to modify the method of Weinstein in view of Antman to incorporate the well known in the art activity such as LD50, ED50, percent absorbed, half-life, and peak concentration for compound activity for more powerful way of predicting potential therapeutic agent.

33. In regard to claim 124, Weinstein describes records corresponding to the molecular targets in the second database are grouped by family, superfamily, or subfamily (page 345, Figure 2, especially, the description describing "cisplatin-carboplatin family").

34. In regard to claim 126, Weinstein describes records corresponding to the molecular targets in the second database are organized by location of expression tissues (page 343, column 2, last two lines, to column 3, line 2, especially, "cancer of breast, prostate, lung...").

35. Claims 77, 122, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al. (1997) (Weinstein hereafter) taken with Antman et al. (1992) (Antman hereafter) as applied to claims 1-3, 10, 14-23, 27, 28, 33-43, 59-64, 67, 68, 70-76, 78-105, 107, 108, 110, 120, 121, 124-129, 132, 139-142, 144, and 145 above, and further in view of Ogata et al. (1999) (Ogata hereafter).

MOTIVATION TO COMBINE

36. Antman et al. discloses an improvement for "better databases" for the treatment of patients in clinical trials (page 240, Conclusions §). Weinstein describes a method of selecting compounds for clinical trials (page 344, column 1, lines 10-16) and providing clinical databases (page 348, column 2, lines 22-23) based on biochemical pathways (page 348, column 1, last paragraph). Ogata describes LIGAND as being tightly integrated with KEGG (biochemical pathways) as well as with most of the major molecular biology databases (Ogata, page 29, column 2, lines 1-6). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by Antman et al. to modify the clinical database of Weinstein by incorporating the pathway information of Ogata for better databases for the treatment of patients in clinical trials.

BASIS FOR REJECTION

37. In regard to claim 77, Weinstein and Antman describe all the limitations of said claims, except for the limitation inositol triphosphate. Ogata describes the limitation of inositol triphosphate (page 30, Table 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use KEGG as described by Weinstein, Ogata, and Antman for better databases for the treatment of patients in clinical trials.

38. In regard to claims 122 and 123, Weinstein and Antman describe all the limitations of said claims, except for the limitation of "sequence alignment" or "sequence homology."

Ogata describes the sequence alignment and homology (Page 33, Column 1, Lines 33 and Figure 3, Table 3, and Page 33, Column 2, Lines 54-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use KEGG as described by Weinstein, Ogata, and Antman for better databases for the treatment of patients in clinical trials.

CONCLUSION

39. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Monks et al. for describing the NCI anti-cancer drug screen.

b. Leming et al. for describing mining the NCI anticancer drug discovery database.

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

41. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

42. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

43. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is 571-272-8300.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo, can be reached on (571) 272-3642.

C. Dune Ly /
Patent Examiner
3/4/07